Title: Methods and Devices For Retrieving
A Subject's Physiological History
From A Biological Sample Analysis
Inventor: Michael Scott Ehrlich
Docket No: C1159.70000US01
Express Mail No: EV292456465US

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OBTAIN A BIOLOGICAL SAMPLE CONTAINING
CELLS HAVING A KNOWN TURNOVER RATE ⎯100

SELECT A CELLULAR MODIFICATION, FOR WHICH:
A) THE AMOUNT INCREASES WITH TIME, AND
B) THE RATE OF INCREASE IS AFFECTED BY
PHYSIOLOGICAL CONDITIONS ⎯110

MEASURE THE AMOUNT OF CELLULAR MODIFICATION
IN EACH OF A PLURALITY OF CELLS ⎯120

SORT THE CELLS AS A FUNCTION OF THEIR CELLULAR
MODIFICATION MEASUREMENTS AND (OPTIONALLY)
GENERATE A CELL DISTRIBUTION PROFILE ⎯130

GENERATE A PHYSIOLOGICAL HISTORY FROM THE
SORTED CELLULAR MEASUREMENTS OR FROM THE
CELL DISTRIBUTION PROFILE ⎯140

USE THE PHYSIOLOGICAL HISTORY TO PROVIDE A DIAGNOSIS,
A PROGNOSIS, OR A THERAPEUTIC RECOMMENDATION ⎯150

Fig. 1

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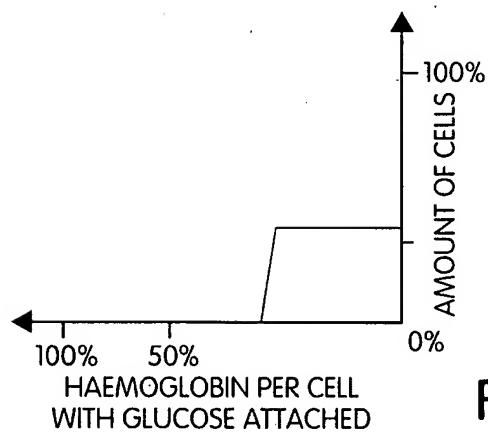
Fig. 2A
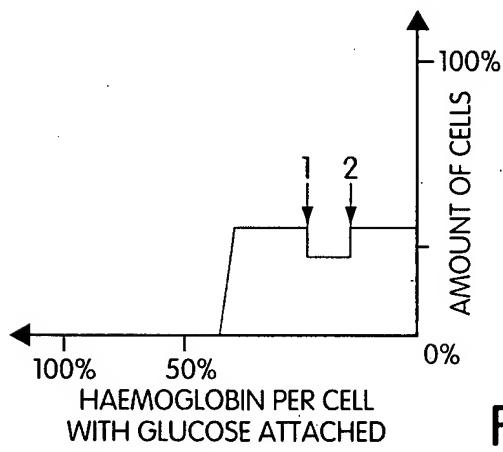
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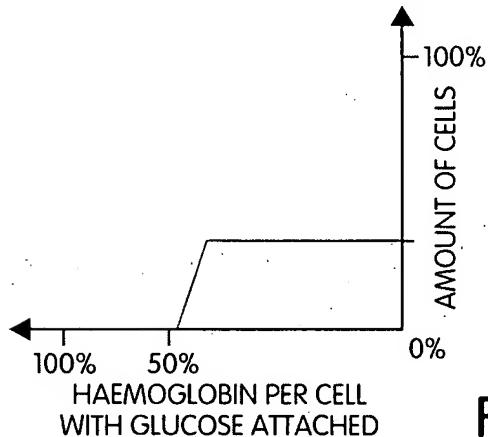

Fig. 2C

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CDP (400mg/dL)
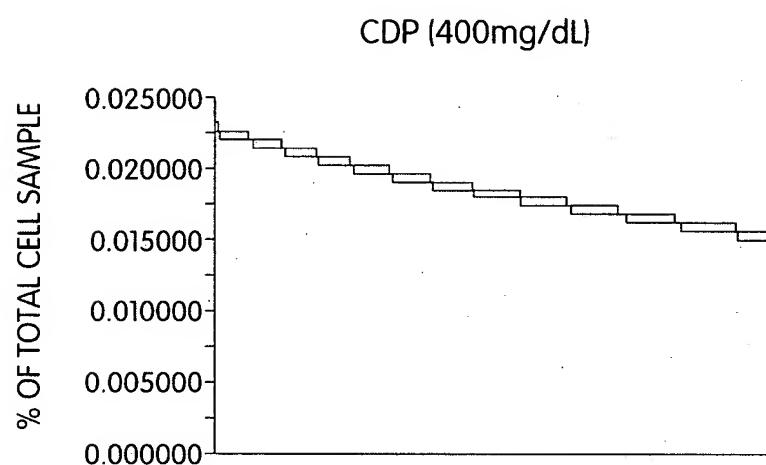
Fig. 3

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```
SELECT A PORTION OF THE CELL DISTRIBUTION
PROFILE (CDP) FOR ANALYSIS                        400
```

```
DIVIDE THE CDP PORTION INTO A
SERIES OF BINS                                    410
```

```
OBTAIN CHANGE IN CELLULAR MODIFICATION
FOR EACH BIN                                      420
```

```
CONVERT THE CHANGE IN CELLULAR MODIFICATION
INTO A PHYSIOLOGICAL VALUE                        430
```

```
GENERATE A PHYSIOLOGICAL HISTORY PROFILE          440
```

to 150
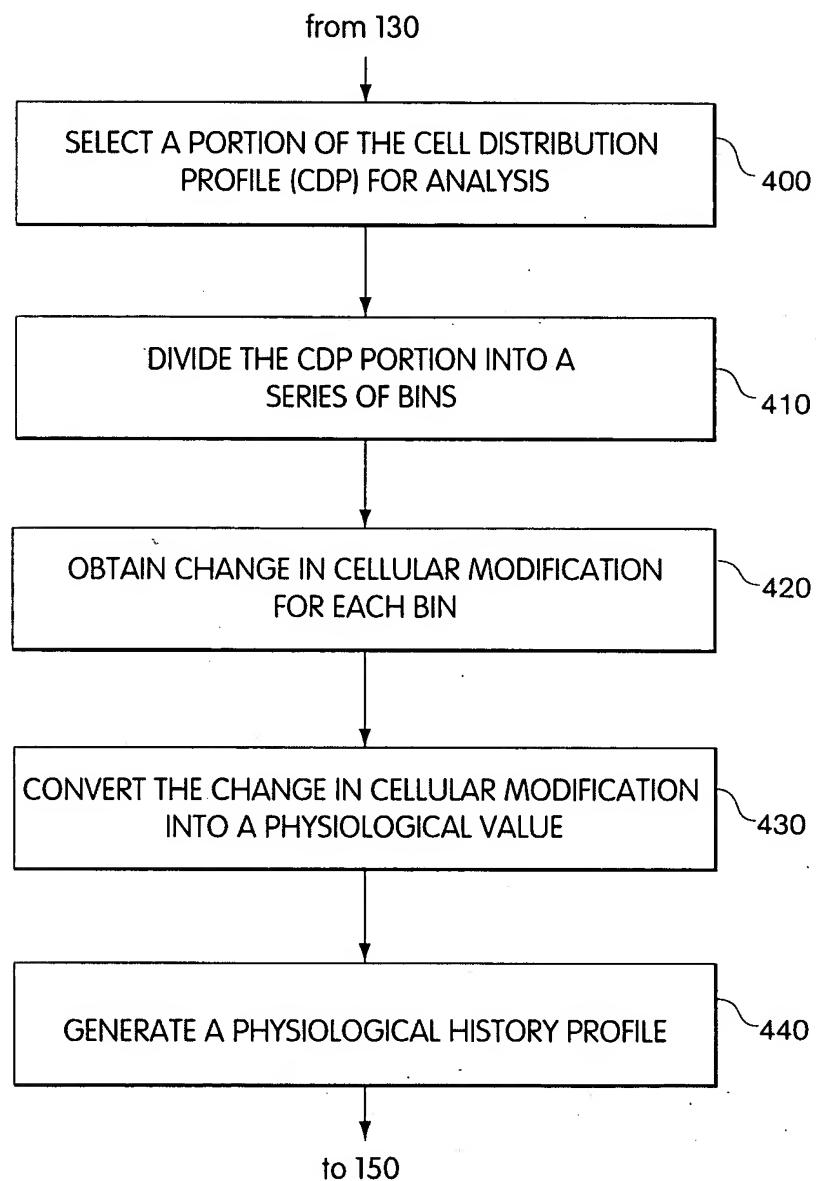
Fig. 4

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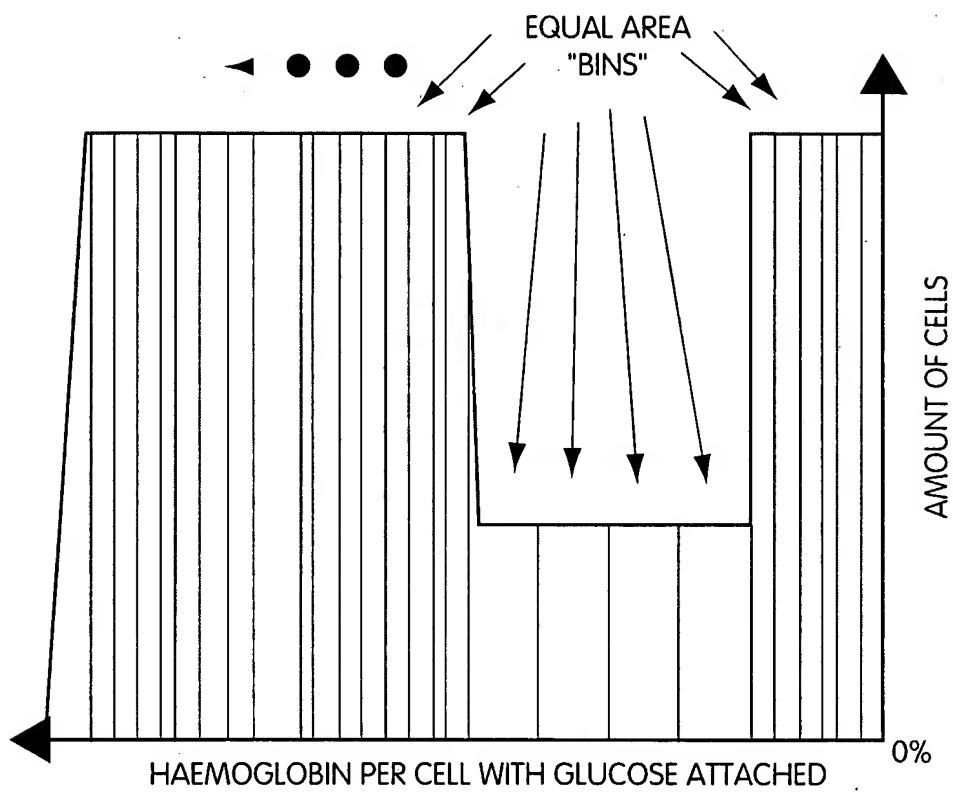
Fig. 5

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SELECT A PORTION OF THE CELL DISTRIBUTION
PROFILE (CDP) FOR ANALYSIS — 600

GENERATE A NUMERICAL OR GRAPHICAL
REPRESENTATION OF THE TEST CDP PORTION — 610

COMPARE THE TEST CDP REPRESENTATION TO ONE
OR MORE REFERENCE REPRESENTATIONS — 620

IDENTIFY ONE OR MORE REFERENCE
REPRESENTATIONS THAT ARE SIMILAR TO
THE TEST REPRESENTATION — 630

DETERMINE A PHYSIOLOGICAL HISTORY PROFILE — 640

to 150
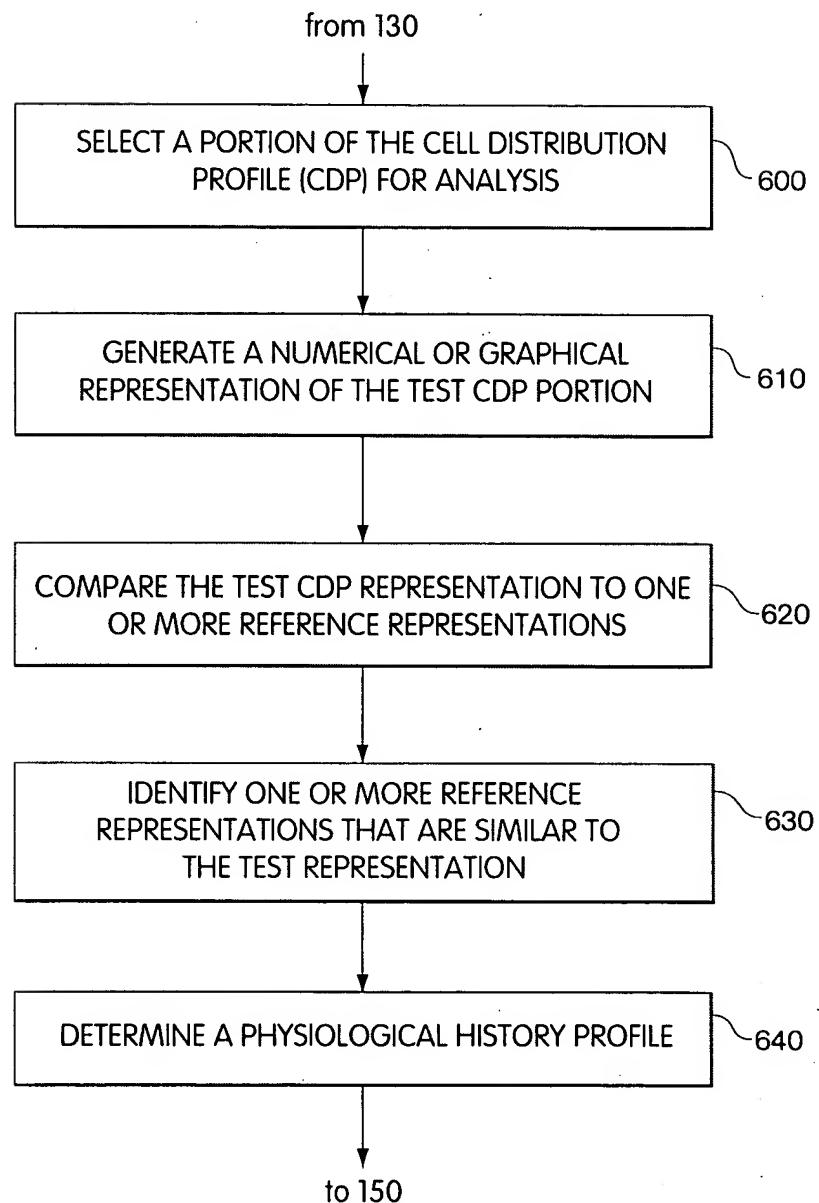
Fig. 6

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SELECT A PORTION OF THE CELL DISTRIBUTION
PROFILE (CDP) FOR ANALYSIS — 700

SELECT A MATHEMATICAL SOLUTION — 710

OBTAIN MODIFICATION VALUES — 720

OBTAIN PHYSIOLOGICAL VALUES — 730

GENERATE A PHYSIOLOGICAL HISTORY PROFILE — 740

to 150
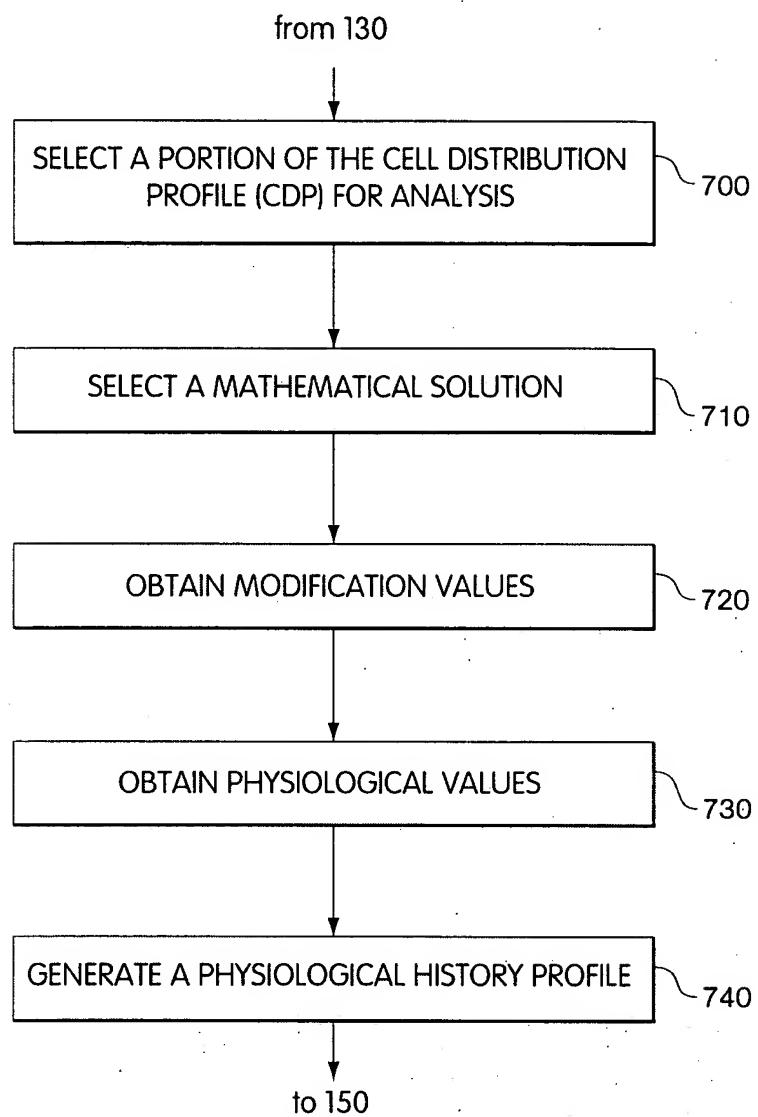
Fig. 7

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Given t_{sp} (where $t_{sp} < 0$) and given T, find $g(t_{sp})$:

Step 1: Solve for X_{sp}

$$t_{sp} = -L \cdot \frac{\sum_{Xsp}^{0} F(X)\Delta X}{\sum_{100\%}^{0} F(X)\Delta X}$$

Step 2: Solve for Ka

$$Ka = \frac{T}{L} \cdot \sum_{100\%}^{0} F(X)\Delta X$$

Step 3: Solve for δ

$$\sum_{Xsp-\frac{\delta}{2}}^{Xsp+\frac{\delta}{2}} F(X)\Delta X = K_a$$

Step 4: Correct for non-linearity

$$r(t_{sp}) = \frac{100\%}{100\% - X_{sp}} \cdot \delta$$

Step 5: Solve for K_b

$$K_b = \frac{K_{rate}}{T}$$

Step 6: Solve for $g(t_{sp})$

$$g(t_{sp}) = K_b \cdot r(t_{sp})$$

Where

$$K_{rate} = 10^8 \frac{mg \cdot s}{dL \cdot \%}$$

Fig. 8

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Given t_{sp} (where $t_{sp} < 0$) and given δ, find $g(t_{sp})$:

Step 1: Solve for X_{sp}

$$t_{sp} = -L \cdot \frac{\sum_{Xsp}^{0} F(X)\Delta X}{\sum_{100\%}^{0} F(X)\Delta X}$$

Step 2: Solve for Ka

$$\sum_{Xsp-\frac{\delta}{2}}^{Xsp+\frac{\delta}{2}} F(X)\Delta X = K_a$$

Step 3: Solve for T

$$T = \frac{Ka \cdot L}{\sum_{100\%}^{0} F(X)\Delta X}$$

Step 4: Correct for non-linearity

$$r(t_{sp}) = \frac{100\%}{100\% - X_{sp}} \cdot \delta$$

Step 5: Solve for K_b

$$K_b = \frac{K_{rate}}{T}$$

Step 6: Solve for $g(t_{sp})$

$$g(t_{sp}) = K_b \cdot r(t_{sp})$$

Where

$$K_{rate} = 10^8 \frac{mg \cdot s}{dL \cdot \%}$$

Fig. 9

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Ka3 = number or "Amount" of cells with % glycation greater than $(\delta 1 + \delta 2)$ and less than $(\delta 1 + \delta 2 + \delta 3)$

Percentage of a Red Blood Cell's Hb that is Glycated
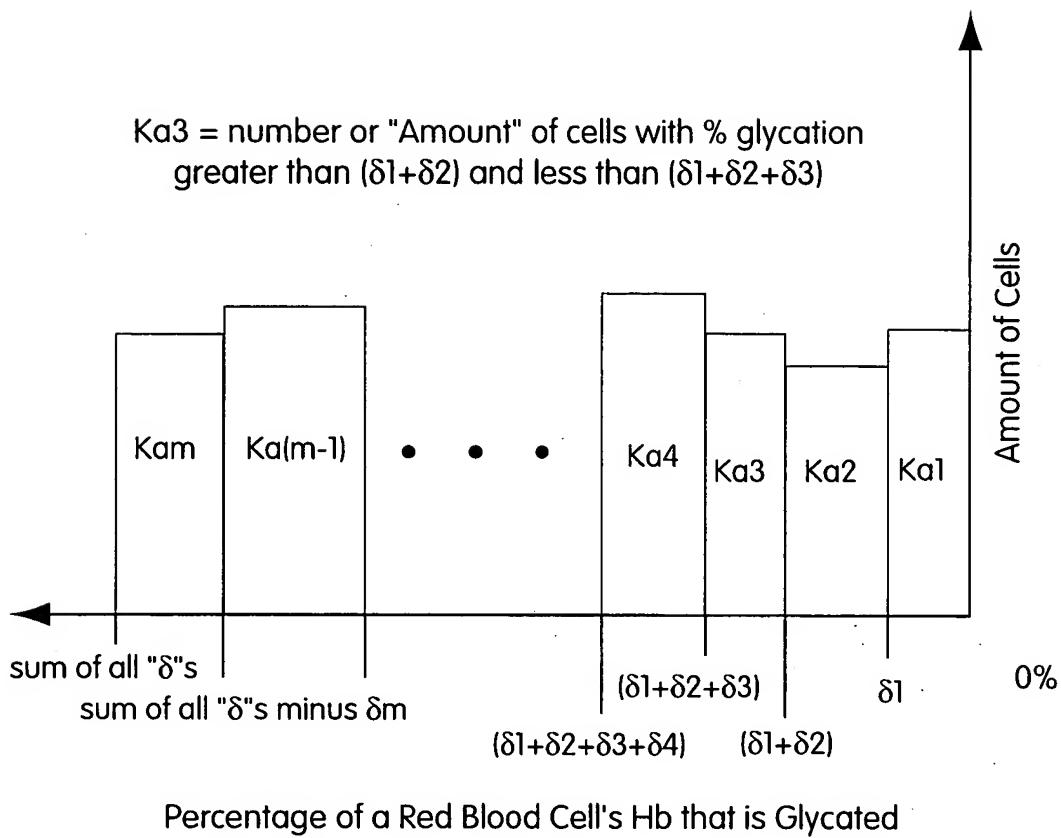
Fig. 10A

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Given δ_1-δ_m and K_{a1}-K_{am}, find t_{sp} and $g(t_{sp})$:

Step 1: Solve for t_{sp}

$$t_{sp} = -L \cdot \frac{\dfrac{K_{sp}}{2} + \sum_{n=sp-1}^{1} K_{an}}{\sum_{n=m}^{1} K_{an}}$$

Step 2: Solve for X_{sp}

$$Xsp = \frac{\delta_{sp}}{2} + \sum_{n=sp-1}^{1} \delta_n$$

Step 3: Solve for T_{sp}

$$T_{sp} = \frac{K_{asp}}{\sum_{n=m}^{1} K_{an}} \cdot L$$

Step 4: Correct for non-linearity

$$r(t_{sp}) = \frac{100\%}{100\% - X_{sp}} \cdot \delta_{sp}$$

Step 5: Solve for K_b

$$K_{bsp} = \frac{K_{rate}}{T_{sp}}$$

Step 6: Solve for $g(t_{sp})$

$$g(t_{sp}) = K_{bsp} \cdot r(t_{sp})$$

Where

$$K_{rate} = 10^8 \, \frac{mg \cdot s}{dL \cdot \%}$$

Fig. 10B

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SAMPLE → [COLUMN] → DYNAMIC LIGHT SCATTERING

Fig. 11A

SEPARATION DOOR

HELIUM INJECTION → [SAMPLE CHAMBER | LONG HIGH-PRESSURE COLUMN] →

DYNAMIC LIGHT SCATTERING

Fig. 11B

EXIT HOLE
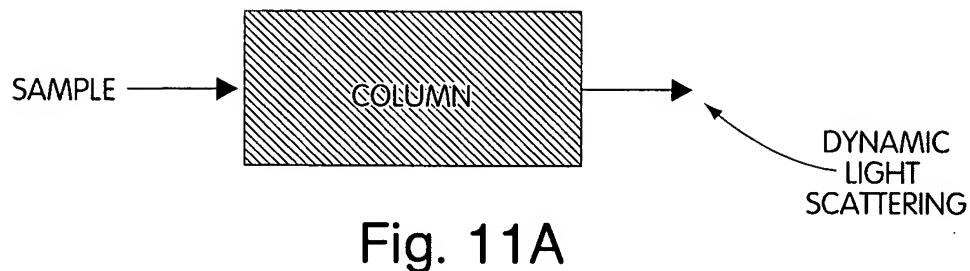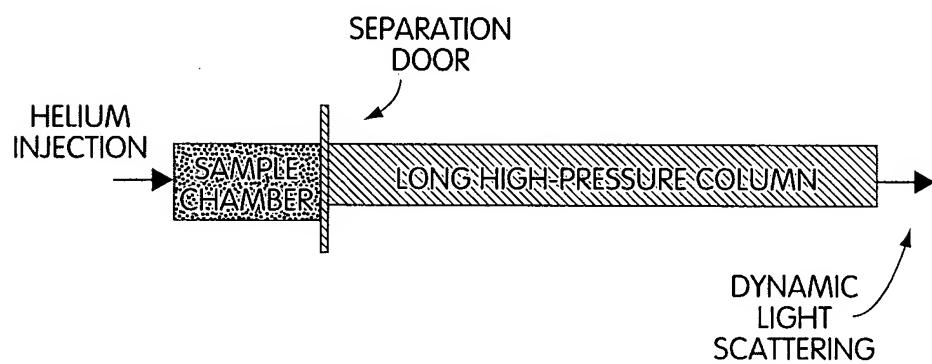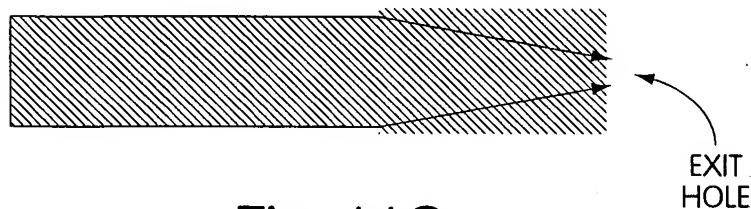
Fig. 11C

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HOT METAL TUBING

GUIDANCE SLEEVE

COLUMN UNDER CONSTRUCTION

Fig. 12A

REPEAT AS NECESSARY

Fig. 12B

COOLANT

COLUMN
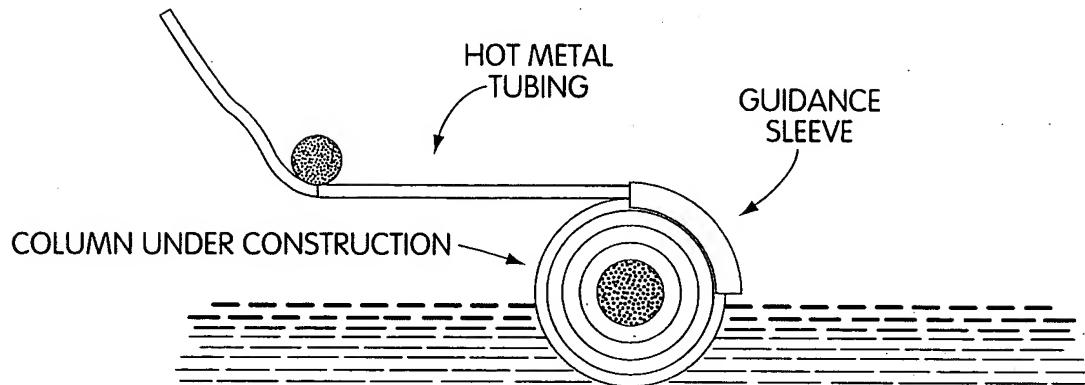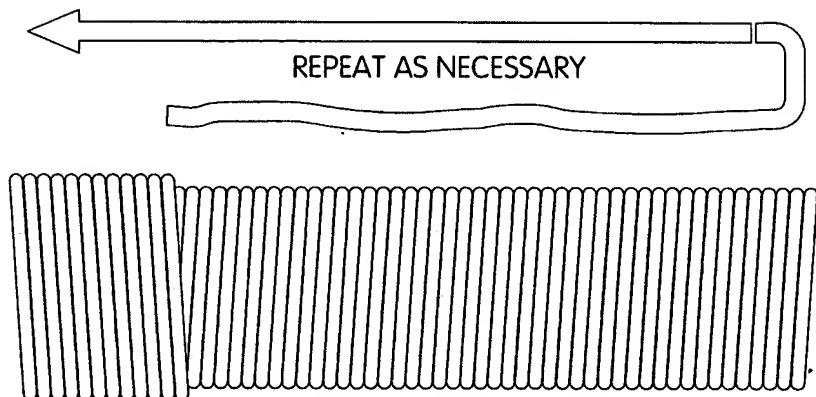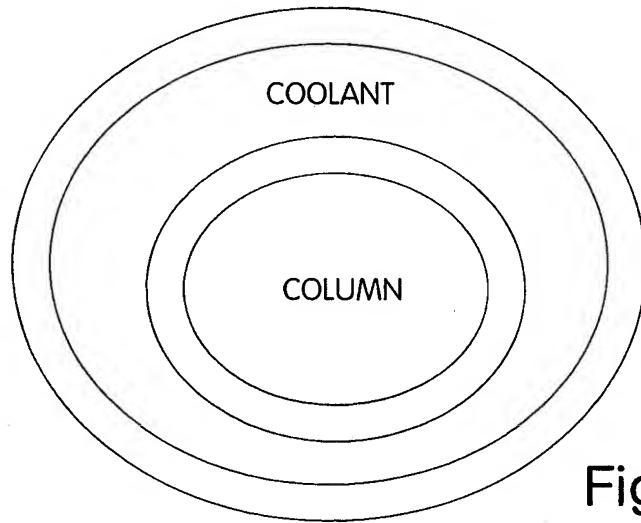
Fig. 12C

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SAMPLE
ENTRY POINT

BUCKETS

E-FIELD

COLUMN

WATER
FLOW

Fig. 13A

PCB OR
SEMICONDUCTOR

ELECTRIC
FIELD

GLASS

COLUMN
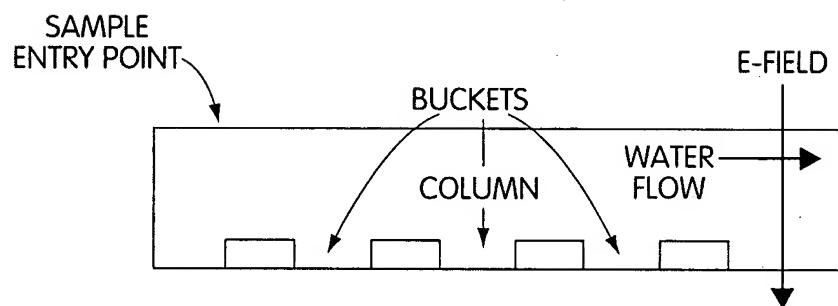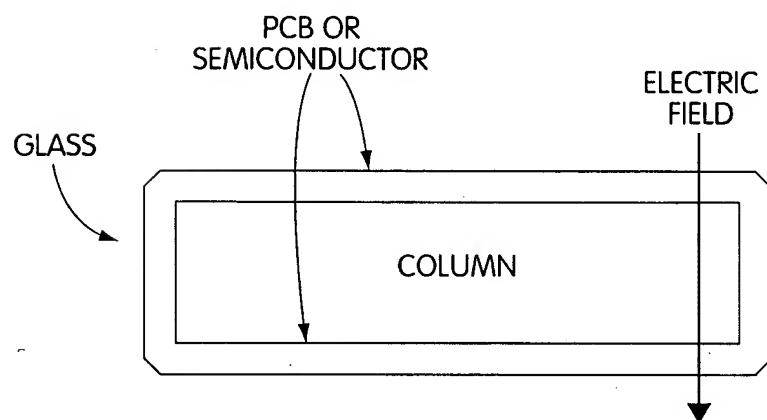
Fig. 13B

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PATIENT WAVEFORM
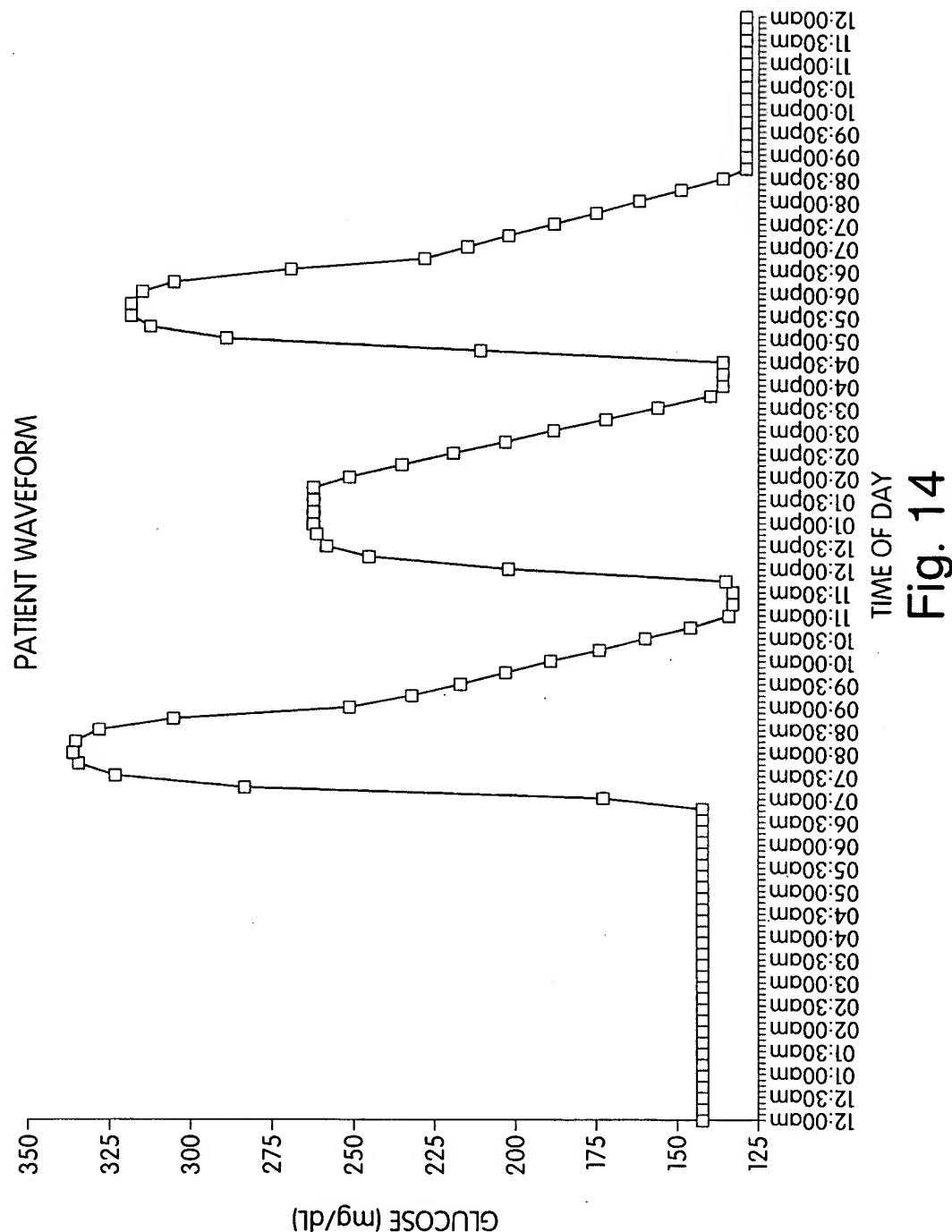
Fig. 14

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CDP
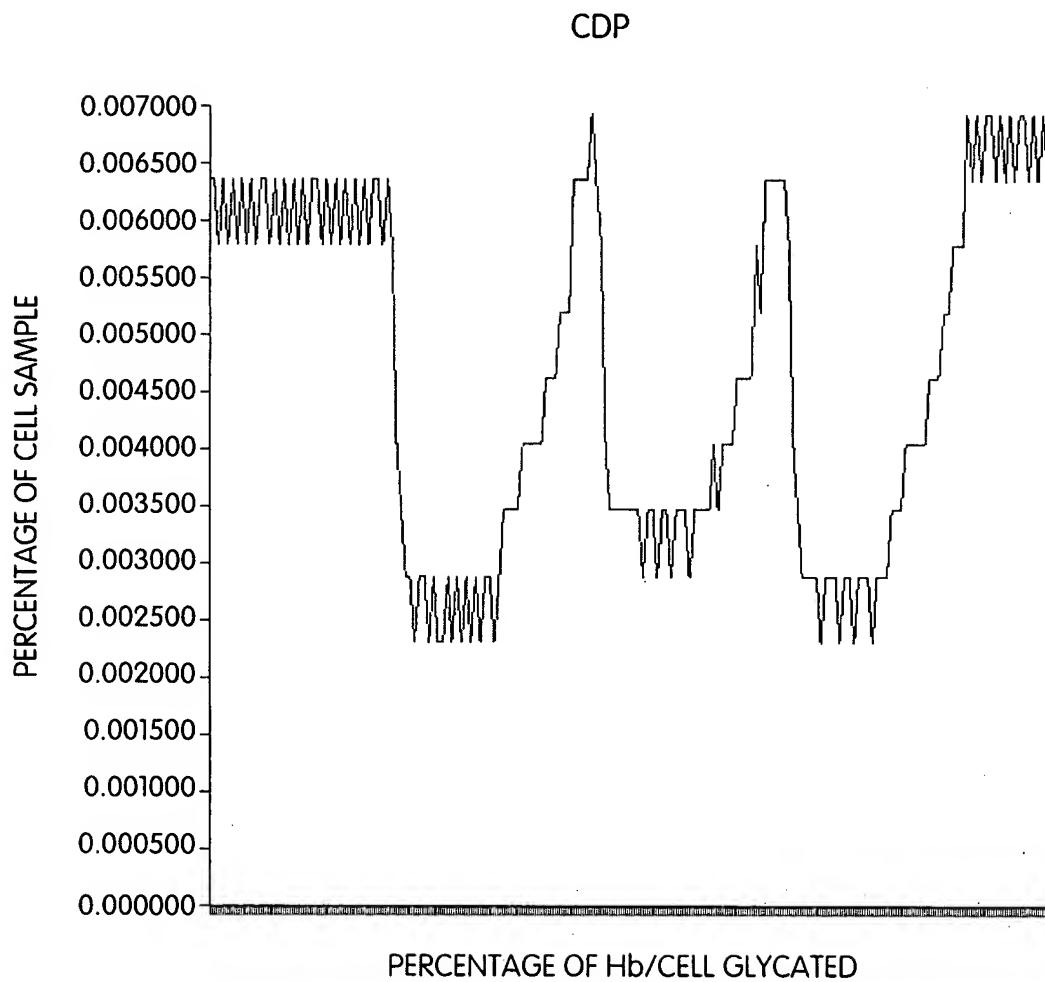
Fig. 15

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GLUCOSE WAVEFORM

Fig. 16